## UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION

MDL NO. 1456 Civil Action No. 01-12257-PBS

Judge Patti B. Saris

## THIS DOCUMENT RELATES TO:

The City of New York v. Abbott Labs., et al. (S.D.N.Y. No. 04-CV-06054)

County of Suffolk v. Abbott Labs., et al.

(E.D.N.Y. No. CV-03-229)

County of Westchester v. Abbott Labs., et al.)

(S.D.N.Y. No. 03-CV-6178)

County of Rockland v. Abbott Labs., et al.

(S.D.Ň.Y. No. 03-CV-7055)

County of Putnam v. Abbott Labs, et al.

(S.D.N.Y. No. 05-CV-04740)

County of Dutchess v. Abbott Labs, et al.

(S.D.N.Y. No. 05-CV-06458)

County of Putnam v. Abbott Labs, et al.

(S.D.N.Y. No. 05-CV-04740)

County of Washington v. Abbott Labs, et al.

(N.D.N.Y. No. 05-CV-00408)

County of Rensselaer v. Abbott Labs, et al.

(N.D.N.Y. No. 05-CV-00422)

County of Albany v. Abbott Labs, et al

(N.D.N.Y. No. 05-CV-00425)

County of Warren v. Abbott Labs, et al.

(N.D.N.Y. No. 05-CV-00468)

County of Greene v. Abbott Labs, et al.

(N.D.N.Y. No. 05-CV-00474)

County of Saratoga v. Abbott Labs, et al.

(N.D.N.Y. No. 05-CV-00478)

County of Columbia v. Abbott Labs, et al.

(N.D.N.Y. No. 05-CV-00867)

Essex County v. Abbott Labs, et al.

(N.D.N.Y. No. 05-CV-00878)

County of Chanango v. Abbott Labs, et al.

(N.D.N.Y. No. 05-CV-00354)

County of Broome v. Abbott Labs, et al.

(N.D.N.Y. No. 05-CV-00456)

County of Onondaga v. Abbott Labs, et al.

(N.D.N.Y. No. 05-CV-00088)

County of Tompkins v. Abbott Labs, et al.

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AND	ì
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REPLY MEMORANDUM OF BAYER CORPORATION
TO PLAINTIFFS' OPPOSITION TO ITS INDIVIDUAL MEMORANDUM IN SUPPORT
OF DEFENDANTS' MOTION TO DISMISS

The plaintiffs concede the principal argument in Bayer's Individual Memorandum in Support of Defendants' Motion to Dismiss. Specifically, plaintiffs acknowledge that Bayer's 2001 and 2003 settlements with New York substantially preclude their claims related to the only Bayer drugs addressed in the text of the Consolidated Complaint of New York City and Plaintiff New York Counties ("Cons. Cmplt.") and the Second Amended Complaint of Nassau County ("Nassau SAC"). The parties disagree only as to whether the plaintiffs' allegations concerning the 2001 and 2003 settlements are sufficient to maintain additional claims directed at other products and time periods not covered by the settlements — even though plaintiffs have made no specific allegations involving those other products or time periods.

The plaintiffs concede that the 2001 settlement bars their claims associated with the alleged inflation by Bayer of the AWPs for its drugs Kogenate and Gamimune from January 1993 through August 1999. (Pls.' Opp. at 2.) Plaintiffs now argue, however, that they have claims "relating to Kogenate and Gamimune for conduct occurring beyond the settlement period." (Pls.' Opp. at 2.) However, as demonstrated in defendants' Memorandum in Support of the Joint Motion to Dismiss, Medicare Part B covered drugs such as Kogenate and Gamimune have been reimbursed by New York based on actual acquisition cost, *not AWP*, during the settlement and post-settlement period.<sup>2</sup> (Defs.' Mem. at 26-27.) Further, plaintiffs fail to allege a single purchase of Kogenate or Gamimune or a single false AWP for either product published during the pre-settlement period. Finally, plaintiffs do not make any allegations that Bayer misreported the best prices or underpaid rebates for Kogenate or Gamimune during any period.

<sup>&</sup>lt;sup>1</sup> Nassau County, which has alleged no purchase of Kogenate (see Nassau SAC Ex. B), does not have standing to assert any claim related to that drug. In re Pharm. Indus. AWP Litig., 263 F. Supp. 2d 172, 193-94 (D. Mass. 2003). Similarly, no plaintiff has standing to pursue claims related to Koate because none has alleged to have purchased that drug. (Cons. Cmplt. Ex. A; Nassau SAC Ex. B).

<sup>&</sup>lt;sup>2</sup> Even if Kogenate and Gamimune were reimbursed by New York based on AWP during the post-settlement period, plaintiffs' claims still must fail because, as plaintiffs acknowledge, Bayer has been required to report to New York the <u>actual average sales price</u> of each of its products during this period. (Cons. Cmplt. ¶ 324; Nassau SAC ¶ 302.)

The plaintiffs also concede that the 2003 settlement bars their best price claims regarding Cipro® from the third quarter of 1995 to the third quarter of 2000 and Adalat® from the second quarter of 1997 to the third quarter of 2000. (Pls.' Opp. at 2.) While plaintiffs now claim that their "Cipro and Adalat claims beyond the period of the 2003 Settlement were not released" (Pls.' Opp. at 2), they have not asserted a single fact suggesting that Bayer misreported rebates or best prices for either Cipro or Adalat at any other time.

Thus, the 2001 and 2003 settlements together bar the only AWP and best price claims plaintiffs assert with even a bare minimum of specificity. To get around this fact, plaintiffs maintain that their allegations concerning the drugs and conduct barred by the settlements are sufficient to allow them to direct fraud claims against every other Bayer product. (Pls.' Opp. at 5.) Plaintiffs' position is inconsistent with Rule 9(b) and this Court's prior rulings. The Court has already held that allegations of a government investigation concerning one product are insufficient to state a claim as against other, unrelated products manufactured by the same company. See In re Pharmaceutical Average Wholesale Price Litig., Memorandum and Order dated November 23, 2004, MDL No. 1456 (D. Mass.) (clarifying that allegation of governmental investigation is sufficient to satisfy Rule 9(b) only as to the particular drug as to which investigation was alleged).

The plaintiffs also urge the Court to sustain their claims against Bayer based on lists appended to their complaints purporting to show the "spread" between "fraudulent AWPs" and "market prices" of certain Bayer drugs published in 2000. (Cons. Cmplt. Exs. A-B; Nassau SAC Exs. A-B.) However, plaintiffs have not disclosed how they calculated the so-called "market prices" or "spread" for any Bayer drug, and thus have no good faith basis for describing any Bayer AWP as "fraudulent." (Cons. Cmplt. ¶ 307-327; Nassau SAC ¶ 288-296.) As this Court has previously instructed, such vague assertions do not satisfy the particularity requirements of Rule 9(b). See In re Pharmaceutical Average Wholesale Price Litig.,

Memorandum and Order dated April 8, 2005, MDL No. 1456 (D. Mass.). Moreover, even if

these bare allegations were sufficient to establish that Bayer reported fraudulent AWPs – which they are not – they "will not suffice to plead a Best Prices fraud." *See In re Pharmaceutical Average Wholesale Price Litig.*, Memorandum and Order dated October 26, 2004, MDL No. 1456 (D. Mass.).

In a last-ditch effort to justify Bayer's continued presence in these matters, plaintiffs state that Bayer has "not dispute[d]" plaintiffs' allegations of unjust enrichment and state statutory violations. (Pls. Opp. at 5.) Not true: Bayer has joined the defendants' Joint Memorandum in Support of Defendants' Motion to Dismiss and Reply Memorandum, which amply illustrate why these claims must be dismissed as against Bayer and each defendant.

In short, plaintiffs admit that Bayer has settled the only claims they have pled with any degree of specificity and have not provided any basis to sustain claims as to products or time periods that are not covered by its settlements.

## CONCLUSION

Bayer respectfully requests that the claims against it in the Consolidated Complaint of New York City and Plaintiff New York Counties and in the Second Amended Complaint of Nassau County be dismissed with prejudice.

Dated: May 11, 2003

Respectfully submitted,

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## **CERTIFICATE OF SERVICE**

I hereby certify that on this 11<sup>th</sup> day of May 2006, I electronically served a true and correct copy of the foregoing on counsel of record by transmission to LNFS pursuant to Case Management Order No. 2.

/s/ Jaime L.M. Jones
Jaime L.M. Jones